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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Collins et al.  
Serial No.: 10/783,020  
Confirmation No.: 3753  
Filed: February 23, 2004  
For: BIFIDOBACTERIUM IN THE TREATMENT OF INFLAMMATORY DISEASE

Examiner: V. Afremova  
Art Unit: 1651

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CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 21<sup>st</sup> day of November 2006.

*Christine M. Colbert*  
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Christine M. Colbert

MAIL STOP AMENDMENT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

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DECLARATION UNDER 37 C.F.R. § 1.132

1. I, Gerald Fitzgerald, am a microbiologist and Professor of Microbiology at University College Cork, Ireland (UCC). A copy of my Curriculum Vitae is attached as Exhibit 1.
2. I have been Director of the National Food Biotechnology Center (NFBC) at UCC from 1998 to 2004. I am co-author of the paper entitled "Determination of Genetic Diversity Within The Genus *Bifidobacterium* and Estimation of Chromosomal Size," by O'Riordan and Fitzgerald (FEMS Microbiology Letters 156 (1997) 259-264), referred to as the O'Riordan and Fitzgerald paper. This paper is cited in the Information Disclosure Statements filed in the referenced application. A copy of this paper is attached as Exhibit 2.

Art Unit 1644

Serial No. 10/354,447  
Conf. No. 8673

3. I am one of the founder members of Alimentary Health and a shareholder in Alimentary Health. Alimentary Health is a campus-based specialty biotechnology company founded in 1999 to commercialize output of research from the UCC/BioResearch Ireland (BRI) probiotic research program. UCC is a shareholder in Alimentary Health. The UCC Probiotic Group and Alimentary Health, as the Group's corporate partner, secured funding from Science Foundation Ireland; the Alimentary Pharmabiotic Centre was formed as a result. My research funding is derived from government grants and industry contracts, the latter primarily with Alimentary Health. My research activities are carried out with UCC, both in APC and Alimentary Health laboratories.

4. I have read the above-identified patent application and the pending claims.

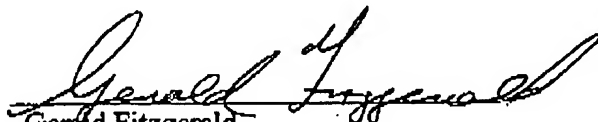
5. The O'Riordan and Fitzgerald paper describes a genetic method to distinguish among different bifidobacterial species. Table 1 of the O'Riordan and Fitzgerald paper lists UCC 35624 as one of the organisms analyzed. It also indicates the source of UCC 35624 is human intestine. UCC35624 is an internal designation given to a strain obtained by researchers in the Department of Microbiology at UCC. One skilled in the art could not have obtained this specific strain using information contained in the O'Riordan and Fitzgerald paper and information available to those in the art at the time the paper was published. The paper is not enabling.

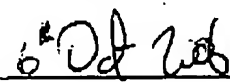
6. Bacterial strain *Bifidobacterium infantis* 35624 was not available to the public. A sample of the strain was not placed in the NCIMB until 1999. Maintenance and control of the strain was managed by the NFBC, under my Directorship. The public did not have access to the strain; anyone who had an interest in obtaining it would have had to make a request to the NFBC, and agree to comply with terms of a strict material transfer agreement before the strain would have been provided. My approval of all requests was required.

Serial No. 10/354,447  
Conf. No. 8673

Art Unit 1644

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above application and any patent or application related thereto.

  
Gerald Fitzgerald

  
Date